

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Semertzides, John et al.

Conf. No: 5748

Serial No. 10/643,664

Group Art Unit: 1615

Filed: August 19, 2003

Examiner: Webman, Edward

For: Composition and Method for the Treatment and Prevention of Adhesions

AMENDMENT

Mail Stop Amendment—*After Filed*
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action, dated July 16, 2007, relating to the above patent application, please consider the following amendment and the accompanying remarks. The amendments herein respond to specific issues raised by the Examiner in the Office Action (see second paragraph on page 3 of the Office Action) and should place the application in form for allowance. Therefore, it should be entered under 37 CFR 1.116.

Listing of the amended claims begin on page 2.

Remarks start on page 4.

Amendments to the Claims

1. - 20. (Cancel)

21. (Currently amended) A method for the treatment and prevention of adhesions in a patient, comprising the steps of:

- a. surgically accessing an animal or human pelvis, abdomen, thorax, pericardium, spinal cord, dura, tendon, tendon sheath, or tissues covered by an epithelial layer where adhesion(s) have formed or may form;
- b. dividing one or more adhesions that may be present or conducting other surgery, thereby forming an injured area;
- c. providing viable epithelial cells and an absorbable protein; and
- d. applying said cells and protein in one or more layers in the form of a liquid, paste or gel directly to said injured area, without the use of scaffolding, to stabilize and temporarily separate the injured area from surrounding organ surfaces.

22. - 27. (Cancel)

28. (Previously presented) The method of claim 21 wherein said viable epithelial cells are harvested from a body cavity.

29. (Previously presented) The method of claim 28 wherein said viable epithelial cells are harvested from the mouth or oral cavity.

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30. - 32. (Cancel)

33. (Previously presented) The method of claim 21 wherein the absorbable protein is fibrin glue.

34. (Previously presented) The method of claim 21 wherein the cells and protein are applied separately to the injured area.

35. (Previously presented) The method of claim 21 wherein the cells and protein are admixed prior to application to the injured area, and the admixture is applied to the injured area.

36. (Previously presented) The method of claim 35 wherein a second layer of absorbable protein is applied over the initial layer of cells and protein mixture.

REMARKS

Claims 21, 28, 29 and 33-36 remain in the present application.

The claims have been amended to define the fact that (1) the cells and glue are applied to the surgical area in the absence of scaffolding and, further (2) to define that the materials are applied as liquids, pastes or gels. No new matter has been added by virtue of these amendments. Antecedent basis for amendment (2) is found in the present application on page 22 in paragraph [060]. Antecedent basis for amendment (1) is found in numerous examples in the application (eg, pages 13-14 in paragraphs [041] and [042] and in fig. 7). In those examples, the cells/glue mixture is applied directly to the surgical area, and while in some embodiments strips or mesh can be used as a covering (although not in the examples noted above), those materials are not used in a structure on which the cells and glue are applied (ie, they are not used as a scaffolding).

The Examiner has maintained his rejection, under 35 USC § 103, based on WO 96/22115 ("WO '115") in view of the US Patent 6,692,738 (MacLaughlin). In repeating that rejection, the Examiner argued that the previously submitted claims did not preclude use of scaffolding or require application of the composition as a liquid. The amendments herein clearly address those issues and, therefore, based on the Examiner's comments, clearly distinguish both the WO '115 and MacLaughlin references.

By specifying that the epithelial cell/protein mixture is deposited directly on the injured area, as a liquid, paste or gel, and in the absence of scaffolding, the method defined by the claims of the present application clearly distinguishes over both references cited by the Examiner. Neither the McLaughlin patent nor WO '115 teaches applying cells directly onto the surface of a

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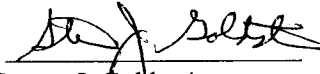
wound site, in the absence of scaffolding, and in the form of a liquid, paste or gel. McLaughlin teaches the building of a "scaffolding" to form new tissue, the cells are not deposited directly onto the wound site. Rather, in McLaughlin the scaffolding holds the cells in a matrix to grow new tissue within the matrix as it is absorbed slowly and allows revascularization. Cells are injected into the scaffolding, but are not deposited directly onto the wound site in the absence of the scaffolding. The scaffolding is clearly a critical element in McLaughlin. WO '115 is somewhat similar in that regard, requiring the use of barrier materials. WO '115 and McLaughlin cannot achieve their result without the use of scaffolding or barrier materials. The application of such materials in surgery is difficult and requires greater time and skill than applying a liquid, paste or gel, as defined by the present claims, directly onto the wound site. Such direct application, in the absence of scaffolding, as required by the present claims, is not envisioned by either reference cited by the Examiner and, therefore, it is submitted that the present claims are allowable over those references. Accordingly, it is respectfully requested that the rejection under § 1 03 be withdrawn.

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In light of the foregoing, it is respectfully submitted that the claims of the present application, as amended herein, are now in form for allowance. Accordingly, reconsideration and allowance of those claims, as amended herein, are earnestly solicited.

Respectfully submitted,

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